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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,659	03/05/2004	Andrew P. Kramer	GUID.150DIV4	3143

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Attn: Mark A. Hollingsworth
Crawford Maunu PLLC
Suite 390
1270 Northland Drive
St. Paul, MN 55120

EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	

MAIL DATE	DELIVERY MODE
10/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,659	KRAMER, ANDREW P.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-17,19-40,43 and 44* is/are pending in the application.

4a) Of the above claim(s) *3,4,9,10,14-16,20,22,23,28,29,33-35,37 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-8,11-13,17,19,21,24-27,30-33,36,38-40,43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

NOTE--This case already contains one RCE. The new rules for RCEs go into effect on November 1, 2007.

Election/Restrictions

Claims 3, 4, 9, 10, 14-16, 20, 22, 23, 28, 29, 33-35, 37, and 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species/inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/15/06.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5-8, 11, 13, 17, 21, 24-27, 30, 36, 38-40, and 43 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sholder (5653738).

Sholder states that the stimulation pulse is provided to the "ventricles" (e.g. col. 7, line 3) and that the system interfaces with the "ventricles" (e.g. col. 9, lines 15-25) and therefore provides for pacing therapy to the left and right ventricles. In addition, when a stimulation pulse is delivered to a ventricle it will cause both ventricles to be paced and therefore will provide pacing therapy to the left and right ventricles. Finally, Sholder discloses a similar amount of disclosure as the applicant in that Sholder and the applicant both just use the word "ventricles" to provide support for pacing the left and right ventricles and neither provide any more disclosure than that.

Sholder also discloses the use his system operating in a DDI mode which will interrupt, initiate or inhibit pulses based on the absence or presence of a sensed event, the use of modifying the PVARP, detecting intrinsic ventricular events/PVC's that disrupt ventricular pacing (e.g. cols. 12, 13), adjusting/increasing/decreasing the PVARP and for two or more cycles (e.g. figure 9, col. 16), and minimizing/avoiding PMTs (e.g. col. 3, line 67).

In the alternative, Sholder discloses the claimed invention except for the pacing therapy being delivered to the left and right ventricles and avoiding PMT. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing system and method as taught by Sholder, with the delivery of the pacing therapy to the left and right ventricles and avoiding PMT since it was known in the art that pacing systems deliver therapy to the left and right ventricles to improve the hearts contraction pattern and augment the

movement of blood through the heart and since it was known that pacing systems should be operated to avoid PMT so that a tachycardia is not produced.

Claims 1, 2, 5-8, 11-13, 17, 19, 21, 24-27, 30-33, 36, 38-40, and 43 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Peterson et al (5893882).

Peterson states that the device paces the "ventricles" (e.g. abstract, col. 2, line 16) and therefore provides for pacing therapy to the left and right ventricles. In addition, when a stimulation pulse is delivered to a ventricle it will cause both ventricles to be paced and therefore will provide pacing therapy to the left and right ventricles. Finally, Peterson discloses a similar amount of disclosure as the applicant in that Peterson and the applicant both just use the word "ventricles" to provide support for pacing the left and right ventricles and neither provide any more disclosure than that.

Peterson also discloses the use of his system operating in a DDD, DDDR, VDD or VDDR mode which will interrupt, initiate, or inhibit pulses based on the absence or presence of a sensed event, the use of modifying the PVARP, detecting intrinsic ventricular events/PVC's that disrupt ventricular pacing, adjusting/increasing/decreasing the PVARP and for two or more cycles (e.g. figures 13 and 14, cols. 30-33), and will inherently minimize/avoid PMTs since the device is meant to treat the patient, not cause a tachycardia, and does not track the atrial rate when the rate goes above the MTR (the upper tracking rate interval--e.g. col. 32, lines 1-10). In addition, Peterson states that ventricular pacing ceases at the MTR/upper tracking rate interval

and therefore will inhibit atrial tracking (e.g. col. 32, line 1) and restores pacing following the transient increase.

In the alternative, Peterson discloses the claimed invention except for the pacing therapy being delivered to the left and right ventricles and avoiding PMT. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing system and method as taught by Peterson, with the delivery of the pacing therapy to the left and right ventricles and avoiding PMT since it was known in the art that pacing systems deliver therapy to the left and right ventricles to improve the hearts contraction pattern and augment the movement of blood through the heart and since it was known that pacing systems should be operated to avoid PMT so that a tachycardia is not produced.

Claims 12, 19, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sholder. Sholder discloses the claimed invention but Sholder does not specifically mention that he restores the pacing following a transient increase in heart rate above a MTR, detects a PMT event and inhibits atrial tracking based on the event, or restores the ventricular pacing as an intrinsic atrial rate decreases below a MTR. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing system and method as taught by Sholder with restoring the pacing following a transient increase in heart rate above a MTR, detecting a PMT event and inhibits atrial tracking based on the event, or restoring the ventricular pacing as an intrinsic atrial rate decreases below a MTR since it was known in the art that pacing systems and methods use: restoring of the pacing following a transient increase in heart rate above a MTR in order to prevent the heart from pacing at a too fast rate when the rate

increases above the MTR and then return to normal pacing when the heart rate decreases below the MTR to decrease PMTs; detecting a PMT event and inhibiting atrial tracking based on the event to prevent a PMT; and restoring of the ventricular pacing as an intrinsic atrial rate decreases below a MTR in order to prevent the heart from pacing at a too fast rate when the rate increases above the MTR and then return to normal pacing when the heart rate decreases below the MTR to decrease PMTs.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5-8, 11-13, 17, 19, 21, 24-27, 30-32, 36, 38-40, and 43 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 14, 16, 17, 19, 22, 23, 28, 29, and 34 of copending Application No. 10/794323 and over claims 1, 2, 6-10, 15-19, 23-27, 31-34, 38-45, 47-49, 53, and 54 of copending Application No. 10/7941511. The claims of the copending applications are narrower and meet the limitations

of the broader application claims. This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed 8/23/07 have been fully considered but they are not persuasive. The argument that Sholder or Peterson does not teach that the pacing timing sequence mitigates the disruption of ventricular pacing is not persuasive since the claims do not contain a limitation to the pacing timing sequence mitigating the disruption of ventricular pacing. In addition, the term "mitigate" is a relative term. The term means to make less harsh or severe the disruption of ventricular pacing, but it is unclear by how much (10%, 20 %, 99%, etc) or relative to what type of pacing (complete loss of ventricular pacing, partial loss of ventricular pacing, etc.). Sholder is used to terminate PMT/PMRR by using a modified pacing timing sequence in order to restore a more constant ventricular rate or ventricular pacing rate and pacing mode using the pacemaker (e.g. col. 3, line 66 to col. 4, col. 11, line 20 and on, etc.) and therefore mitigates the disruption of ventricular pacing. It is noted that the claim does not state how much the modified pacing sequence "mitigates" the disruption of ventricular pacing and relative to what period it is mitigated (i.e. immediately, during modified pacing, in the long run {such as in Sholder}, etc). In addition, the applicant's argument that Peterson does not teach that his modified pacing timing sequence mitigates the disruption of ventricular pacing is not persuasive for the same reasons given above in regards to Sholder. Peterson modifies his pacing timing sequence in order to restore a more constant ventricular rate or ventricular pacing rate and mode in the long run. The argument on page 11 that Sholder teaches that a P-wave is blocked and that the modified pacing timing sequence in Sholder is therefore not configured to mitigate

the disruption of ventricular pacing is not persuasive since the claim is an open-ended comprising claim and does not preclude the use of additional structure or steps as seen in Sholder.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762

10/19/7

GRE
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